

1 JOSEPH N. AKROTIRIANAKIS (Bar No. 197971)

2 *jakro@kslaw.com*

3 CARTER L. GEORGE (Bar No. 308775)

4 *cgeorge@kslaw.com*

5 KING & SPALDING LLP

6 633 West Fifth Street, Suite 1600

7 Los Angeles, CA 90071

8 Telephone: (213) 443-4355

9 Facsimile: (213) 443-4310

10 KATHLEEN E. MCCARTHY (*pro hac vice*)

11 *kmccarthy@kslaw.com*

12 KENNETH FOWLER (*pro hac vice*)

13 *kfowler@kslaw.com*

14 KING & SPALDING LLP

15 1185 Avenue of the Americas, 34th Floor

16 New York, NY 10036

17 Telephone: (212) 556-2100

18 Facsimile: (213) 556-2222

19 Attorneys for Defendant AMGEN INC.

20 **UNITED STATES DISTRICT COURT**

21 **CENTRAL DISTRICT OF CALIFORNIA**

22 SANDOZ INC.,

23 Plaintiff,

24 v.

25 AMGEN INC.,

26 Defendant.

Case No. 2:22-cv-05326-RGK-MAR

**DEFENDANT AMGEN INC.'S
[CORRECTED] REPLY IN SUPPORT OF
MOTION FOR SUMMARY JUDGMENT**

Date: Monday, June 26, 2023

Time: 9:00 a.m.

Place: Courtroom 850

TABLE OF CONTENTS

		Page(s)
1		
2		
3	I. ARGUMENT	1
4	A. Sandoz Cannot Receive a Presumption of Injury.	1
5	B. Sandoz Has No Evidence of Lost Sales Caused by Amgen’s Promotions.....	5
6	C. Sandoz Has No Evidence of Reputational Harm or Corrective Advertising	
7	Damages Caused by Amgen.	8
8	D. Without Injury, Sandoz Is Not Entitled to Disgorgement.....	9
9	E. Sandoz Cannot Receive an Injunction.	10
10	II. CONCLUSION	10
11		
12		
13		
14		
15		
16		
17		
18		
19		
20		
21		
22		
23		
24		
25		
26		
27		
28		

TABLE OF AUTHORITIES

Page(s)

Cases

BMMG, Inc. v. Am. Telecast Corp.,
42 F.3d 1398 (9th Cir. Dec. 1, 1994).....2

Campagnolo S.R.L. v. Full Speed Ahead, Inc.,
2010 WL 455195 (W.D. Wash. Feb. 1, 2010)2

Carter v. Clark Cty.,
459 F. App'x 635 (9th Cir. 2011).....9

Certified Nutraceuticals Inc. v. Clorox Co.,
2021 WL 4460806 (S.D. Cal. Sept. 29, 2021)7

CKE Rest. v. Jack in the Box, Inc.,
494 F. Supp. 2d 1139 (C.D. Cal. 2007).....3

Falcon Stainless, Inc. v. Rino Cos.,
2011 WL 13130703 (C.D. Cal. Oct. 21, 2011)3, 4

FLIR Sys. v. Sierra Media, Inc.,
903 F. Supp. 2d 1120 (D. Or. 2012).....2

Fortress Secure Sols. LLC v. AlarmSIM LLC,
2019 WL 7816820 (E.D. Wash. 5, 2019).....2

Grasshopper House, LLC v. Clean & Sober Media LLC,
2019 WL 12074086 (C.D. Cal. July 1, 2019)7, 8

Grasshopper House, LLC v. Clean & Sober Media, LLC,
2021 WL 3702243 (9th Cir. 2021)9, 10

Harper House, Inc. v. Thomas Nelson, Inc.,
889 F.2d 197 (9th Cir. 1989)1, 3

Ira Green, Inc. v. J.L. Darling, Corp.,
2012 WL 4793005 (W.D. Wash. Oct. 9, 2012).....3

King Tuna, Inc. v. Anova Food, Inc.,
2009 WL 10673202 (C.D. Cal. Jan. 28, 2009).....3, 7

1	<i>Kurin, Inc. v. Magnolia Med. Techs.,</i>	
2	473 F. Supp. 3d 1117 (S.D. Cal. 2020)	3
3	<i>Lexmark Int’l, Inc. v. Static Control Components, Inc.,</i>	
4	572 U.S. 118 (2014).....	8, 10
5	<i>Merck Eprova AG v. Gnosis S.p.A.,</i>	
6	760 F.3d 247 (2d Cir. 2014)	2, 4
7	<i>Monster Energy Co. v. Integrated Supply Network, LLC,</i>	
8	533 F. Supp. 3d 928 (C.D. Cal. Apr. 12, 2021).....	9
9	<i>Munchkin, Inc. v. Luv N’ Care, Ltd.,</i>	
10	2015 WL 12672088 (C.D. Cal. Jan. 21, 2015).....	7
11	<i>Munchkin, Inc. v. Playtex Prods., LLC,</i>	
12	2012 WL 12886205 (C.D. Cal. Oct. 4, 2012)	2, 4
13	<i>Nat’l Prods., Inc. v. Gamber-Johnson LLC,</i>	
14	699 F. Supp. 2d 1232 (W.D. Wash. Mar. 16, 2010)	2
15	<i>Nutrition Distribution LLC v. PEP Res., LLC,</i>	
16	2019 WL 652391 (S.D. Cal. Feb. 15, 2019).....	3
17	<i>Out of the Box Enters. v. El Paseo Jewelry Exch.,</i>	
18	2012 WL 12893690 (C.D. Cal. May 11, 2012).....	3
19	<i>Playboy Enter. v. Baccarat Clothing Co.,</i>	
20	692 F.2d 1272 (9th Cir. 1982)	9
21	<i>Pom Wonderful LLC v. Ocean Spray Cranberries, Inc.,</i>	
22	2011 WL 4852472 (C.D. Cal. Oct. 12, 2011)	4
23	<i>Quidel Corp. v. Siemens Med. Sols. USA,</i>	
24	2020 WL 4747724 (S.D. Cal. Aug. 17, 2020).....	3, 4, 9
25	<i>Quidel Corp. v. Siemens Med. Sols. USA,</i>	
26	2021 WL 4622504 (9th Cir. 2021)	2, 3
27	<i>Reed v. NBTY, Inc.,</i>	
28	2014 WL 12284044 (C.D. Cal. Nov. 18, 2014)	7
	<i>Skydive Arizona, Inc. v. Quattrocchi,</i>	
	673 F.3d 1105 (9th Cir. 2012)	5

1	<i>Southland Sod Farms v. Stover Seed Co.</i> ,	
2	108 F.3d 1134 (9th Cir. 1997)	2, 3, 8
3	<i>ThermoLife Int’l, LLC v. Gaspari Nutrition Inc.</i> ,	
4	648 F. App’x 609 (9th Cir. 2016)	2
5	<i>Time Warner Cable, Inc. v. DIRECTV, Inc.</i> ,	
6	497 F.3d 144 (2d Cir. 2007)	2
7	<i>TrafficSchool.com, Inc. v. Edriver Inc.</i> ,	
8	653 F.3d 820 (9th Cir. 2011)	<i>passim</i>
9	<i>Trekeight, LLC v. Symantec Corp.</i> ,	
10	2006 U.S. Dist. LEXIS 100609 (S.D. Cal. May 23, 2006)	8
11	<i>Trekeight, LLC v. Symantec Corp.</i> ,	
12	2006 WL 5201349 (S.D. Cal. May 23, 2006)	8
13	<i>Trovan, Ltd. v. Pfizer, Inc.</i> ,	
14	2000 WL 709149 (C.D. Cal. May 24, 2000)	8
15	<i>TYR Sport, Inc. v. Warnaco Swimwear, Inc.</i> ,	
16	709 F. Supp. 2d 802 (C.D. Cal. 2010)	2
17	<i>U-Haul Int’l, Inc. v. Jartran, Inc.</i> ,	
18	601 F. Supp. 1140 (D. Ariz. 1984)	4
19	<i>U-Haul Int’l, Inc. v. Jartran, Inc.</i> ,	
20	681 F.2d 1159 (9th Cir. 1982)	4
21	<i>Vitamins Online, Inc. v. HeartWise, Inc.</i> ,	
22	2019 WL 6682313 (D. Utah. Sept. 24, 2019)	4
23	<i>Vyas v. Vyas</i> ,	
24	2017 WL 3841809 (C.D. Cal. Sept. 1, 2017)	7
25	<i>W. States Wholesale, Inc. v. Synthetic Indus., Inc.</i> ,	
26	206 F.R.D. 271 (C.D. Cal. 2002)	2
27	<i>W. Sugar Coop. v. Archer-Daniels-Midland Co.</i> ,	
28	2015 WL 12683192 (C.D. Cal. Aug. 21, 2015)	4
	<i>Williams & Cochrane, LLP v. Rosette</i> ,	
	2022 WL 4544711 (S.D. Cal. Sept. 27, 2022)	2

REPLY

If Sandoz’s theory of its case were accurate, Sandoz would have *some* evidence of injury—a survey or testimony from *any* customer who purchased Amgen’s product in lieu of Sandoz’s because of Amgen’s promotional materials. Sandoz has no such evidence, so it misstates documents and asks the Court simply to *presume* injury. But Sandoz’s own cases show it is not entitled to a presumption of injury because the facts provide no basis to assume that a sale of Neulasta® Onpro® equals a lost sale of Ziextenzo®. The Court therefore should grant Amgen summary judgment.

I. ARGUMENT

A. Sandoz Cannot Receive a Presumption of Injury.

Sandoz stakes most of its opposition on claiming a presumption of injury. But while a presumption makes sense “where it’s reasonable to presume that *every* dollar [the] defendant makes has come directly out of plaintiff’s pocket,” *TrafficSchool.com, Inc. v. Edriver Inc.*, 653 F.3d 820, 831 (9th Cir. 2011), this is not such a case. No presumption exists where, as here, “advertising does not directly compare defendant’s and plaintiff’s products” and “numerous competitors participate in a market,” because it is not reasonable to assume any “particular competitor” was injured. *Harper House, Inc. v. Thomas Nelson, Inc.*, 889 F.2d 197, 209 n.8 (9th Cir. 1989). Sandoz’s contrary arguments—that a presumption of injury exists for *all* literally false ads (Opp. 6-8) and that Amgen’s promotions directly compare the parties’ products (Opp. 9-11)—conflict with every relevant case, including those Sandoz cites. This Court should reject Sandoz’s charade: no presumption of injury applies to cure Sandoz’s lack of evidence.

1. Sandoz’s first argument confuses the presumption of *deception* for literally false advertisements with the distinct presumption of *injury*. As the Ninth Circuit held in *Harper House*, a “presumption of consumer deception” is different than “a presumption of the fact of injury.” 889 F.2d at 209-10. *Harper House* held the defendant was entitled to a presumption of deception but *not* a presumption of injury. *Id.* Since then, the Ninth Circuit and other courts have consistently held that “a presumption that

1 the consumers are in fact deceived . . . does not extend to justify a finding that a
2 competitor is injured by the deception.” *BMMG, Inc. v. Am. Telecast Corp.*, 42 F.3d
3 1398 (Table), at *1 (9th Cir. Dec. 1, 1994). Thus, while literal falsity may create “a
4 presumption of actual deception,” it does *not* alone create a presumption of “injury.”
5 *TYR Sport, Inc. v. Warnaco Swimwear, Inc.*, 709 F. Supp. 2d 802, 817 (C.D. Cal. 2010).¹

6 Even the cases Sandoz cites make this point. *TrafficSchool*, 653 F.3d at 831, states
7 a presumption of injury *does not apply* “when advertising does not directly compare
8 defendant’s and plaintiff’s products.” *Southland Sod Farms v. Stover Seed Co.*, 108
9 F.3d 1134, 1146 (9th Cir. 1997), likewise limits the presumption to “comparative
10 advertisement claims.” The non-binding opinion in *ThermoLife Int’l, LLC v. Gaspari*
11 *Nutrition Inc.*, 648 F. App’x 609, 615-16 (9th Cir. 2016), relied on *TrafficSchool* and
12 *Southland Sod*, and it did not purport to extend the presumption beyond direct
13 comparative advertisements.² Sandoz also misleadingly quotes Second Circuit cases
14 that actually limit the presumption to “false comparative advertising” in a “two-player
15 market.” *Merck Eprova AG v. Gnosis S.p.A.*, 760 F.3d 247, 259-61 (2d Cir. 2014); *see*
16 *Time Warner Cable, Inc. v. DIRECTV, Inc.*, 497 F.3d 144, 161-62 (2d Cir. 2007)
17 (presumption for “comparative advertisement”).³

18
19 ¹ *Williams & Cochrane, LLP v. Rosette*, 2022 WL 4544711, at *20-21 (S.D. Cal. Sept.
20 27, 2022); *Munchkin, Inc. v. Playtex Prods., LLC*, 2012 WL 12886205, at *1-2 (C.D.
21 Cal. Oct. 4, 2012); *Campagnolo S.R.L. v. Full Speed Ahead, Inc.*, 2010 WL 455195, at
22 *2 (W.D. Wash. Feb. 1, 2010); *W. States Wholesale, Inc. v. Synthetic Indus., Inc.*, 206
23 F.R.D. 271, 278 (C.D. Cal. 2002).

24 ² The Ninth Circuit after *ThermoLife* still holds “[t]he presumption is inapplicable when . . .
25 the ‘advertising does not directly compare defendant’s and plaintiff’s products.’” *Quidel*
26 *Corp. v. Siemens Med. Sols. USA (Quidel II)*, 2021 WL 4622504, at *2 (9th Cir. 2021).

27 ³ The district court decisions Sandoz cites do the same. *FLIR Sys. v. Sierra Media, Inc.*,
28 903 F. Supp. 2d 1120, 1132-33 (D. Or. 2012) (presumption for “false comparative
advertising”); *Fortress Secure Sols. LLC v. AlarmSIM LLC*, 2019 WL 7816820, at *9
(E.D. Wash. 5, 2019) (presumption for “direct comparative advertising”); *Nat’l Prods.,*
Inc. v. Gamber-Johnson LLC, 699 F. Supp. 2d 1232, 1242 (W.D. Wash. Mar. 16, 2010)
(same); *cf. Rosette*, 2022 WL 4544711, at *21 (recognizing *FLIR* “is limited to false
comparative advertisements”). *Nutrition Distribution LLC v. PEP Res., LLC*, 2019 WL

Sandoz also claims false or misleading ads create a presumption of injury when the parties are “direct competitors” (Opp. 7), but this language comes from *TrafficSchool*, which held the presumption does not apply to non-comparative ads, where it is not “reasonable to presume that every dollar” one competitor earns “has come directly out of” the other competitor’s “pocket.” 653 F.3d at 831. Courts in this Circuit consistently enforce this limit,⁴ and Sandoz cites no case holding otherwise. Sandoz thus cannot invoke a presumption of injury without establishing the promotions “directly compare[d]” Onpro® and Ziextenzo®. *Quidel II*, 2021 WL 4622504, at *2.

2. Sandoz cannot do so. It concedes this is not a “two-player market,” *Quidel I*, 2020 WL 4747724, at *11, because there have always been four to seven competitors. (SUF ¶ 3.) And outside of a two-player market, ads are “comparative” for purposes of the presumption of injury only when they “directly compare” two parties’ products. *TrafficSchool*, 653 F.3d at 831 (emphasis added).⁵ Amgen’s promotions made no such “direct comparison.” *Falcon Stainless, Inc. v. Rino Cos.*, 2011 WL 13130703, at *15 (C.D. Cal. Oct. 21, 2011). Sandoz concedes the promotions do not mention Ziextenzo®. (SUF ¶ 2.) Even on Sandoz’s interpretation, the Retrospective Study promotion compares Onpro® to Neulasta® PFS plus *multiple* biosimilars.⁶ The

652391, at *5-6 (S.D. Cal. Feb. 15, 2019), held the presumption did not apply, and so it is of little help in deciding when the presumption *does* apply. To the extent *Ira Green, Inc. v. J.L. Darling, Corp.*, 2012 WL 4793005, at *11 (W.D. Wash. Oct. 9, 2012), could be read to hold *Southland Sod* supports a presumption of injury from non-comparative ads, *Southland Sod* expressly states otherwise. 108 F.3d at 1146.

⁴ *Quidel Corp. v. Siemens Med. Sols. USA (Quidel I)*, 2020 WL 4747724, at *9-11 (S.D. Cal. Aug. 17, 2020); *Kurin, Inc. v. Magnolia Med. Techs.*, 473 F. Supp. 3d 1117, 1144 (S.D. Cal. 2020).

⁵ *Quidel II*, 2021 WL 4622504; *Harper House*, 889 F.2d at 209 n.8; *Out of the Box Enters. v. El Paseo Jewelry Exch.*, 2012 WL 12893690, at *13 (C.D. Cal. May 11, 2012); *King Tuna, Inc. v. Anova Food, Inc.*, 2009 WL 10673202, at *5 (C.D. Cal. Jan. 28, 2009); *CKE Rest. v. Jack in the Box, Inc.*, 494 F. Supp. 2d 1139, 1145-46 (C.D. Cal. 2007).

⁶ Sandoz offers no evidence regarding how the relevant audience *in fact* interpreted the ad. Sandoz’s evidence (mostly hearsay) is at best speculation about how some readers *could* interpret the ad. (Opp. 10 (citing to speculation from “experts” who did not conduct

1 Prospective Study promotion likewise compares Onpro® to many alternative
2 treatments that merely “include[d]” Ziextenzo®. (Opp. 10.)

3 Courts have unanimously held that such promotions referring to multiple unnamed
4 competitors do not support a presumption of injury (Mot. 15 n.8)—including in cases
5 Sandoz cites. *Pom Wonderful LLC v. Ocean Spray Cranberries, Inc.*, 2011 WL 4852472,
6 at *3 (C.D. Cal. Oct. 12, 2011) (cited at Opp. 9) (rejecting presumption because ad
7 referred to “generic product or class of products”).⁷ Sandoz cites no contrary case. The
8 ads in *U-Haul Int’l, Inc. v. Jartran, Inc.*, 601 F. Supp. 1140, 1147 (D. Ariz. 1984),
9 compared the parties’ products by name.⁸ And *Merck* and *Time Warner* both involved a
10 “two-player market.” *Merck*, 760 F.3d at 259-61; see *Munchkin*, 2012 WL 12886205, at *5
11 (holding *Time Warner* does not apply when market lacks “a ‘nearly binary structure’”).⁹
12 None of this leaves Sandoz without a remedy; it just requires Sandoz to have proof.

13 surveys and cannot speak for others.) And some of that speculation (including the FDA
14 letter) guesses consumers might interpret the ad to refer to *all* Neulasta® biosimilars,
15 not Ziextenzo® specifically. That is not enough for a presumption of injury.

16 ⁷ See *Falcon*, 2011 WL 13130703, at *15 (no presumption because ad “made
17 comparisons to five other products”). Sandoz is wrong that *Falcon* addressed only the
18 amount of damages. (Opp. 11 n.8.) *Falcon* rejected a presumption as to whether the
19 defendant “was injured.” 2011 WL 13130703, at *14.

20 ⁸ Sandoz claims (Opp. 9 n.6) the Ninth Circuit in *U-Haul* held an ad was comparative
21 because it “implicitly compared” two products, but that decision had nothing to do with
22 a presumption of injury. *U-Haul Int’l, Inc. v. Jartran, Inc.*, 681 F.2d 1159, 1159-60 (9th
23 Cir. 1982). *U-Haul* also involved a two-player market. *Id.*; see *Quidel I*, 2020 WL 4747724,
24 at *10 (ads not “implicitly comparative” when market had more than two competitors).

25 ⁹ The unpublished district court decision in *W. Sugar Coop. v. Archer-Daniels-Midland*
26 *Co.*, 2015 WL 12683192, at *1 (C.D. Cal. Aug. 21, 2015), is *sui generis* because it was
27 a lawsuit between “the sugar industry and the corn-refining industry.” “[T]rade groups[]
28 and associations” representing the “sugar industry” sued an “association[]” representing
the “corn and [high-fructose corn syrup] industry.” *Id.* Because the parties were industry-
wide associations, when the defendant association ran an ad promoting corn syrup over
“sugar,” that was a direct reference to the plaintiff associations’ product, not a class of
products that merely *included* a particular party’s product. See *id.* at *4-5; *Vitamins*
Online, Inc. v. HeartWise, Inc., 2019 WL 6682313, at *13 (D. Utah. Sept. 24, 2019)
(holding *W. Sugar* ads “specifically ‘targeted and drew comparisons between its product
and [the plaintiffs’] competing product’”). Those unique facts are far afield from this case.

B. Sandoz Has No Evidence of Lost Sales Caused by Amgen's Promotions.

Sandoz needs the Court to invent a presumption because it has no evidence of injury.¹⁰ Sandoz's brief is rife with incomplete citations, misquotes taken out of context, and inadmissible hearsay; but even if Sandoz's evidence were admissible, it reflects nothing more than that some customers used Onpro® or did not use Ziextenzo®. (Mot. 13-15.) *Not one* of the documents Sandoz cites reflects that any customer chose Neulasta® Onpro® in lieu of Ziextenzo® because of Amgen's promotions or would have chosen Ziextenzo® *instead of* Onpro® but for Amgen's promotions. One document discusses a customer who stuck with Onpro®, but it does not mention Ziextenzo® or suggest the customer would have switched *from* Onpro® *to* Ziextenzo® but for Amgen's promotions. (Benoff Exh. M.) Another document discusses a payer that maintained access to Onpro®, but it does not mention Ziextenzo® or suggest Ziextenzo® would have profited from Onpro®'s removal. (Benoff Exh. N.)¹¹ And while Sandoz cites hearsay emails indicating customers appreciated Amgen's promotions or continued buying Onpro®, none suggests a customer chose Neulasta® *over* Ziextenzo® as opposed to any other treatment and most also refer to price, discounts and Onpro® benefits. (Benoff Exhs. BB, GG, HH, NN.)

Sandoz also distorts the relevant timeline. It claims "Amgen knew [its purported] scheme was likely to be successful" because of Amgen's "HCP survey." (Opp. 3.) But that survey was conducted in July 2020, *after* Amgen commissioned the Neulasta® studies and authorized the relevant promotions. (Benoff Exh. KK.)¹² Amgen

¹⁰ Sandoz argues evidence is not required (Opp. 13), but the cases it quotes addressed different issues. *TrafficSchool* described the standard for Article III standing, not the elements of a Lanham Act claim. 653 F.3d at 825. *Skydive Arizona, Inc. v. Quattrocchi*, 673 F.3d 1105, 1112-23 (9th Cir. 2012), addressed proof of "the *amount* of damages," which is "held to a lower standard" than "the *fact* of damages."

¹¹ Ziextenzo® was not on the payer's formulary at the time and thus could not have benefitted from any loss to Onpro®. (Supp. Akro. Exh. CC at 434.)

¹² Moreover, the "HCP survey" proves nothing because it did not show or ask about the relevant promotions, let alone include any of the context that appears in the promotions; instead, the survey asked a small subset of healthcare providers, who had already treated patients with Onpro® in the past month, whether they were aware of certain "data."

1 commissioned the Prospective Study in 2017 (Supp. Akro. Exh. DD at 439),
2 commissioned the Retrospective Study in 2019 (Supp. Akro. Exh. EE at 442), and
3 approved the Retrospective Study promotion in February 2020 (Supp. Akro. Exh. FF at
4 473). The HCP study obviously could not have affected Amgen’s decision to
5 commission studies or approve promotions it commissioned and approved years or
6 months *earlier*. Similarly, Sandoz contends that, “[d]espite Amgen’s wide proliferation
7 of ‘the 31% claim’ and other promotional messages surrounding its studies, Amgen
8 employees readily acknowledged the ruse for what it was.” (Opp. 3.) But the document
9 Sandoz cites analyzed Neulasta®’s performance in late 2017—*years before* the relevant
10 promotions ever existed. (Benoff Exh. D.)¹³

11 Sandoz’s speculation that Amgen prevented it from *entering* the Neulasta®
12 biosimilar market (Opp. 16) fares no better. Sandoz’s only evidence is its claim
13 Ziextenzo® “fell well short of its anticipated market share goals . . . in 2020.” (*Id.*) But
14 the documents Sandoz cites contain no hint that Ziextenzo® missed its sales goals
15 *because of* Amgen’s promotions. (Benoff Exhs. OO, PP.) To the contrary, Ziextenzo®
16 sales had already fallen far short of Sandoz’s goals *before Amgen published its promotions*.

17
18
19 (Supp. Akro. Exh. GG at 477, 494-495.) The survey did not ask the few respondents
20 who answered “yes” *how* they became aware—from scientific abstracts, colleagues,
21 promotional materials, or another source. Sandoz also asserts “Amgen’s internal
22 analysis confirms that Amgen’s promotional materials contributed to the sale of 89,000
23 additional units of Neulasta® in 2020.” (Opp. 14 n.12.) That is a misrepresentation: the
24 estimate related to *all* of Amgen’s promotional efforts (including TV ads) for
25 Neulasta®, not just the promotions at issue here. (Benoff Exh. MM at 902.)

26 ¹³ Sandoz also asserts Amgen “doubled down on its use of the Retrospective Study in
27 its advertising campaigns, even after receiving the FDA’s letter” (Opp. 4), but Amgen
28 began removing the Retrospective Study promotion *months before* FDA sent its letter
(Supp. Akro. Exh. HH at 500.) Sandoz’s “evidence” of “doubling down” is an interim
update to Amgen’s sales team just days after Amgen received the Untitled Letter, which
said Amgen was evaluating the letter. (Benoff Exh. V.) Amgen thereafter agreed to
continue executing its prior decision to stop using all Retrospective Study promotions.
(Supp. Akro. Exh. II [Exhibit 125] at 503.) That is not “doubling down.”

1 (Supp. Akro. Exh. JJ at 512, Exh. FF at 473; Benoff Exhs. OO at 911-12, PP at 916.)¹⁴
2 Sandoz’s internal documents assigned blame for that shortfall to multiple self-imposed
3 factors, but *never* to Amgen’s promotions. (Mot. 6-8.) And Ziextenzo®’s sales later
4 *exceeded* Sandoz’s expectations, even though Amgen continued using some of the
5 relevant promotions. (Supp. Akro. Exh. KK at 522); *see Certified Nutraceuticals Inc.*
6 *v. Clorox Co.*, 2021 WL 4460806, at *6-7 (S.D. Cal. Sept. 29, 2021) (no “causation”
7 when plaintiff’s “sales actually increased”).

8 Finally, Sandoz relies on its expert reports (Benoff Exhs. EE, LL), but the reports
9 are unsworn and thus “not admissible to support or oppose summary judgment.” *King*
10 *Tuna*, 2009 WL 10673202, at *5.¹⁵ Sandoz’s damages expert, moreover, is an economist
11 with no qualifications to opine whether Sandoz’s evidence proves the fact of injury and
12 causation. *Grasshopper House, LLC v. Clean & Sober Media LLC*, 2019 WL 12074086,
13 at *11 (C.D. Cal. July 1, 2019).¹⁶ Anyway, he identifies no documentary evidence that
14 anyone ever chose Onpro® in lieu of Ziextenzo® because of Amgen’s promotions.
15 *Reed v. NBTY, Inc.*, 2014 WL 12284044, at *4 (C.D. Cal. Nov. 18, 2014) (refusing to
16

17 ¹⁴ Sandoz argues Onpro®’s share increased “following the launch of its false advertising
18 campaign” (Opp. 16), but that does not suggest the promotions *caused* the increase, let
19 alone that sales of Onpro® would have gone to Ziextenzo® instead. The increase
20 coincided with the COVID-19 pandemic, which indisputably benefitted Onpro®
21 because it allowed patients to avoid a trip to the hospital or clinic. (Akro Exh. P at 246-
22 47); Supp. Akro. Exh. LL at 524-526.) Sandoz inaccurately claims two Amgen
23 documents “attributed” Onpro®’s 2020 sales to the relevant promotions (Opp. 16), but
24 one document is about projections *for 2021* (Benoff Exh. QQ), and the other includes
25 promotional efforts other than the promotions at issue here (Benoff Exh. RR). A third
26 document Sandoz cites merely notes that Amgen promoted real-world clinical evidence
27 while Onpro®’s share *declined* by 1% in the previous quarter. (Benoff Exh. SS at 925).

28 ¹⁵ *Accord Vyas v. Vyas*, 2017 WL 3841809, at *5 (C.D. Cal. Sept. 1, 2017); *Munchkin,*
Inc. v. Luv N’ Care, Ltd., 2015 WL 12672088, at *2 (C.D. Cal. Jan. 21, 2015).

¹⁶ Sandoz’s marketing expert is a marketing professor who has no foundation to opine
on injury or causation at all, and he offers no methodology for his opinions. (Benoff
Exh. LL at 786.) These are just a few of the fatal flaws in Sandoz’s expert reports, as
Amgen will establish in *Daubert* motions. But the Court need not reach *Daubert* here
due to Sandoz’s failure to present evidence essential to its claims.

1 “assume that the experts have accurately quoted or characterized ... documents”). He
2 instead *assumes* Amgen’s promotions were a cause of Sandoz’s lost sales, then purports to
3 analyze the *amount* of lost sales attributable to the promotions. (Benoff Exh. EE at 370
4 n.1, 397.) That makes his report useless for proving the *fact* (rather than the *amount*) of
5 injury for purposes of summary judgment. *Grasshopper*, 2019 WL 12074086, at *11.¹⁷

6 **C. Sandoz Has No Evidence of Reputational Harm or Corrective**
7 **Advertising Damages Caused by Amgen.**

8 Without evidence of lost sales, Sandoz argues it may proceed based on harm to
9 reputation and costs associated with corrective advertising. (Opp. 16-17.) But Sandoz
10 has no evidence it has *suffered* those harms, let alone that Amgen *caused* them.

11 Sandoz has no evidence of what its reputation is or that its reputation has suffered.
12 That is no surprise, since Amgen’s promotions do not refer to Sandoz or Ziextenzo®
13 “by name” or “equat[e] [Ziextenzo®] with an inferior product.” *Lexmark Int’l, Inc. v.*
14 *Static Control Components, Inc.*, 572 U.S. 118, 138 (2014) (cleaned up). Sandoz cites
15 two documents discussing Onpro®’s “benefits,” but neither mentions Sandoz or Ziextenzo®
16 or suggests any customer thought less of them because of Amgen’s promotions. (Benoff
17 Exhs. UU, VV.)¹⁸ To the contrary, Ziextenzo®’s sales are better now than ever before.

18 As for corrective advertising, it is recoverable only when there is “some evidence
19

20 ¹⁷ Sandoz’s cases are inapposite. The expert evidence in *Southland Sod*, 108 F.3d at 1146,
21 included “consumer survey testimony,” which Sandoz lacks. The expert evidence in
22 *Trekeight, LLC v. Symantec Corp.*, 2006 U.S. Dist. LEXIS 100609, at *27-28 (S.D. Cal.
23 May 23, 2006), created “a triable issue” only as to whether the parties “compete[d].” It
24 also addressed only the *amount* of injury; the plaintiff still had to prove the *fact* of injury
25 and causation. *Trekeight, LLC v. Symantec Corp.*, 2006 WL 5201349, at *4 (S.D. Cal.
26 May 23, 2006). It did so with evidence, lacking here, that customers chose the
27 defendant’s product over the plaintiff’s product *because of* the defendant’s ads.
28 *Trekeight*, 2006 U.S. Dist. LEXIS 100609, at *28-29.

¹⁸ In the only case Sandoz cites, the defendant’s trademark infringement associated the
plaintiff’s product with a deadly drug, which the court held was equivalent to “slander
per se.” *Trovan, Ltd. v. Pfizer, Inc.*, 2000 WL 709149, at *12 (C.D. Cal. May 24, 2000).
Sandoz does not claim Amgen created any such association.

1 that the allegedly false advertising likely caused an injury making th[e] corrective
2 advertising necessary.” *Quidel I*, 2020 WL 47447724, at *8 (cleaned up). Sandoz “has
3 no evidence that it was damaged by” Amgen’s promotions, so it “cannot now recover for
4 amounts spent correcting that advertising.” *Id.* That aside, Sandoz’s own expert admits
5 he has “not seen any corrective advertising aimed at clearing up any misperceptions that
6 were created by” Amgen’s promotions. (Benoff Exh. LL at 831.) All Sandoz cites is an
7 interrogatory response (Benoff Exh. TT) that does not identify any corrective
8 advertising—only internal expenses that no more qualify as advertising than does this
9 lawsuit. Sandoz’s “uncorroborated and self-serving” interrogatory response cannot create
10 “a genuine issue” for trial. *Carter v. Clark Cty.*, 459 F. App’x 635, 636 (9th Cir. 2011).

11 **D. Without Injury, Sandoz Is Not Entitled to Disgorgement.**

12 The Ninth Circuit’s binding decision in *TrafficSchool* forecloses Sandoz’s
13 argument it can receive disgorgement even in the absence of injury. *TrafficSchool* held
14 disgorgement without proof of injury is “appropriate” only in “false comparative
15 advertising cases” or in “palming-off” cases where “ordinary damages won’t deter
16 unlawful conduct” because the “defendant associates its product with plaintiff’s
17 noncompetitive product to appropriate good will or brand value.” 653 F.3d at 831.¹⁹
18 Amgen’s promotions do not “directly compare” the parties’ products, *id.*, and Sandoz
19 does not claim Amgen appropriated its goodwill or brand value. Sandoz thus cannot
20 recover disgorgement absent “proof of past injury or causation.” *Id.*²⁰

21 ¹⁹ Sandoz seeks to expand *TrafficSchool*’s lack-of-deterrence category through an
22 incomplete quotation. (Opp. 18.) The full quotation reads: “[Disgorgement] is also
23 appropriate where ordinary damages won’t deter unlawful conduct: *for example, when*
24 *defendant associates its product with plaintiff’s noncompetitive product to appropriate*
25 *good will or brand value.*” *TrafficSchool*, 653 F.3d at 831 (emphasis added). The other
26 cases Sandoz cites are both palming-off trademark infringement cases. *Playboy Enter.*
27 *v. Baccarat Clothing Co.*, 692 F.2d 1272, 1274-75 (9th Cir. 1982); *Monster Energy Co.*
28 *v. Integrated Supply Network, LLC*, 533 F. Supp. 3d 928, 933 (C.D. Cal. Apr. 12, 2021).

²⁰ The non-binding decision in *Grasshopper House, LLC v. Clean & Sober Media, LLC*,
2021 WL 3702243 (9th Cir. 2021), did not and could not overrule *TrafficSchool*. Its
discussion of damages and disgorgement related to different ads and evidence, so lack of

E. Sandoz Cannot Receive an Injunction.

Sandoz cannot receive an injunction because it cannot prove a “likelihood of future injury.” *Lexmark*, 572 U.S. at 135. Sandoz does not dispute that if (as is the case) Amgen has stopped using the Retrospective Study promotion, it cannot support an injunction. (Mot. 18.) Instead, Sandoz claims information from the Retrospective Study appears on a single (non-promotional) webpage. (Opp. 19.) But Sandoz offers no evidence Amgen has directed any customer to the page since 2021 or that customers can access the page via links on Amgen’s website. To the contrary, the website Sandoz references does *not* link to the promotion. (Supp. Akro. ¶¶ 12-13 & Exh. MM.) As for the Prospective Study promotion, Sandoz argues only that it is “false and misleading” (Opp. 19), which is not enough to show Sandoz is *likely to be injured*. Sandoz has no proof it has ever been injured by the Prospective Study promotion, and Ziextenzo® has now captured *more* market share than it expected before Amgen began using the Prospective Study promotion. (Supp. Akro. Exh. KK at 522.) Particularly with Ziextenzo® now exceeding even Sandoz’s expectations, Sandoz cannot show it is likely to be injured in the future.

II. CONCLUSION

The Court should grant the motion and enter judgment for Amgen. At minimum, should the Court conclude that Sandoz has established a genuine dispute as to disgorgement or future harm, it should enter partial judgment as a matter of law on Sandoz's damages claims for monetary relief and hold a bench trial on injunctive relief.

Dated: June 12, 2023

KING & SPALDING LLP

By: /s/Joseph N. Akrotirianakis

Attorneys for Defendant AMGEN INC.

injury from one ad would not foreclose disgorgement with respect to another. *Compare id.* at *2 (damages “from the Process and Mission Statements”), *with id.* at *3 (disgorgement “independently of ... the Process Statement”). The plaintiff quantified the exact number of viewers for the relevant ad, and the defendant conceded each view caused it a measurable benefit. *Id.* at *4. There is no similar evidence or concession here.

LOCAL RULE 11-6.2 CERTIFICATE OF COMPLIANCE

The undersigned, counsel of record for Amgen Inc., certifies that this brief contains 4,893 words, which complies with the word limit of L.R. 11-6.1.

Dated: June 12, 2023

KING & SPALDING LLP

By: /s/Joseph N. Akrotirianakis
JOSEPH N. AKROTIRIANAKIS

Attorneys for Defendant AMGEN INC.